IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

PFIZER INC., PFIZER IRELAND PHARMACEUTICALS, WARNER-LAMBERT COMPANY, and WARNER-LAMBERT COMPANY LLC,	
Plaintiffs,	Civil Action No. 1:08-07231
v.	Consolidated with Civil Action No. 1:09-cv-6053
APOTEX INC. and APOTEX CORP.,	Judge Robert M. Dow Jr.
Defendants.	Magistrate Judge Martin C. Ashman

MEMORANDUM IN SUPPORT OF
APOTEX INC. AND APOTEX CORP.'S MOTION TO COMPEL DISCOVERY

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Defendants Apotex Inc. and Apotex Corp. (collectively, "Apotex") respectfully submit this memorandum in support of their motion to compel discovery from Plaintiffs Pfizer Inc., Pfizer Ireland Pharmaceuticals, Warner-Lambert Company and Warner Lambert Company LLC (collectively, "Pfizer").

INTRODUCTION

Pending before this Court as of June 29, 2010 were two motions to dismiss: (1) Defendants Apotex Inc. and Apotex Corp.'s FED. R. CIV. P. 12(b)(1) and (6) Motion to Dismiss (09-cv-6053 Docket Item No. ("D.I.") 34)[1], and (2) Plaintiff Pfizer's Motion to Dismiss Defendant Apotex's Counterclaims ("Pfizer's motion to dismiss") (D.I. 113). On October 27, 2009, this Court ordered discovery to proceed "focused primarily on [U.S. Patent No. RE40,667 E] as to which no motion to dismiss is pending or anticipated." (D.I. 109, Minute Order at 1). On June 30, 2010, the Court denied each party's motion to dismiss with qualification, and a status conference has been set for July 27, 2010. (D.I. 141-145).

Each party has propounded discovery requests in the form of Rule 33 interrogatories and Rule 34 requests for production, produced documents, and responded to interrogatories, and discovery is proceeding. The parties, however, have reached an impasse on certain discoverable documents Apotex is seeking from Pfizer. In particular, Apotex is seeking from Pfizer: (1) all agreements, licenses, and/or contracts Pfizer has entered into with any third-party regarding the marketing of generic atorvastatin calcium, including settlement agreements Pfizer reached with Ranbaxy Laboratories Ltd., Ranbaxy Pharmaceuticals, Inc., Teva Pharmaceuticals USA, Inc., and/or Cobalt Pharmaceuticals, Inc. ("third-party generic atorvastatin agreements"); and (2) all documents involving generic entry into the atorvastatin market, including market share

[1] This action (No. 1:08-cv-7231) has been consolidated with an identical transferred Delaware action that was assigned Civil Action No. 1:09-cv-6053. All docket item references shall be to items on the main 08-cv-7231 docket unless otherwise specified.

projections, strategy plans, life-cycle plans, and documents reflecting any anticipated reaction by Pfizer to generic entry ("generic entry documents").

This information is relevant to the claims and defenses raised in this litigation relating to U.S. Patent No. RE40,667 E ("the '667 patent"). Specifically, as pointed out in Apotex's opposition brief (D.I. 68) to Pfizer's motion to dismiss (D.I. 113), after the first atorvastatin ANDA-filer, Ranbaxy, defeated the patent that reissued in the '667 patent (*see Pfizer, Inc. v. Ranbaxy Labs. Ltd.*, 457 F.3d 1284, 1286 (Fed. Cir. 2006)), Pfizer was mysteriously able to convince Ranbaxy to stay off the market through a settlement agreement ***for over twenty (20) months after the date Ranbaxy would have otherwise been able to enter the market*** (March 24, 2010, the expiration date of U.S. Patent No. 4,681,893 plus pediatric exclusivity). (*See* D.I. 68, Apotex's Mem. of Law in Opp'n to Pls.' Mot. to Dismiss Defs.' Countercls. ("Apotex's MTD Opp'n Br.") 8 n.4). Was this because of the '667 patent? Did Ranbaxy stipulate to the patentability of the subject matter claimed in the '667 patent and that any commercial success for Lipitor® was tied to the '667 patent? Was any license involved? Was Ranbaxy under threat of suit from Pfizer on U.S. Patent Nos. 5,686,104 ("the '104 patent"), 5,969,156 ("the '156 patent"), and/or 6,126,971 ("the '971 patent"), the three later-expiring Lipitor® patents which are the subject of counterclaims Apotex has asserted that Pfizer had moved the Court to dismiss because "Pfizer has given no indication that it will ever sue Apotex or any other party on the ['104, '156, and '971 patents]?" (D.I. 56, Mem. in Supp. of Pls.' Mot. to Dismiss Defs.' Countercls. ("Pls.' MTD Br.") 13). This information, along with any other agreements Pfizer has entered into with third-parties regarding generic atorvastatin, is clearly relevant to Apotex's invalidity defenses and counterclaim on the '667 patent (D.I. 110, Answer, Defenses, Countercl. and Jury Demand at Sixth Defense and Countercl. ("Answer") Count X).

Further, Pfizer has pleaded for permanent injunctive relief. In order to obtain a permanent injunction, Pfizer will be required to prove the existence of the traditional factors that warrant injunctive relief, including irreparable harm. *See eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 391-92 (2006). The generic entry documents Apotex seeks from Pfizer directly speak to whether or not Pfizer will be irreparable harmed by the entry of generic competition in the atorvastatin market.

For at least the foregoing reasons, more fully explained below, the Court should order Pfizer to produce third-party generic atorvastatin agreements and generic entry documents immediately.

MATERIAL FACTS

I. The '667 Patent.

The '667 patent issued on March 17, 2009. (09-cv-6053 D.I. 25-1, First Am. Compl. Ex. B, '667 patent at cover). On March 23, 2010, Pfizer filed the operative complaint in this action—the First Amended Complaint, originally filed in the transferred Delaware action—which asserted, *inter alia*, a claim for infringement of the '667 patent against Apotex and sought an injunction "permanently enjoining Apotex . . . from making, using, selling, offering to sell, or importing the atorvastatin calcium product described in Apotex's ANDA No. 90-548 until . . . expiration of the '667 patent." (09-cv-6053 D.I. 25, First Am. Compl. ¶¶ 51-56 and request for relief ¶ D). On October 28, 2009, at this Court's direction, Apotex answered the First Amended Complaint and filed a counterclaim with invalidity and non-infringement counts directed to the '667 patent. (D.I. 110, Answer, Countercl. Counts IX and X). Apotex twice laid out in painstaking detail its invalidity defenses to the '667 patent in its Paragraph IV certification notice letter, served on March 18, 2010, and in its Response to Pfizer Interrogatory No. 4, served on February 19, 2010, including an invalidity defense under 35 U.S.C. § 103(a) for obviousness of

the '667 patent over the prior art. (Alul Decl. Ex. A, Apotex's Mar. 18, 2010 Paragraph IV notice letter to Pfizer; *id*. at Ex. B, Apotex's Resp. to Pfizer Interrog. No. 4)[2]. In response to Apotex's invalidity defense and counterclaim based on obviousness, Pfizer has stated that it will rely on purported "secondary considerations" of non-obviousness in order to support the validity of the '667 patent. (Alul Decl. Ex. H, Pfizer Resp. to Apotex Interrog. No. 6).

II. Apotex Request Nos. 114-115 and 122-123.

On December 11, 2009, Apotex propounded its First Set of Requests for the Production of Documents and Things to Plaintiffs (Alul Decl. Ex. C). Apotex Request Nos. 114-115 and 122-123 recite as follows:

> **REQUEST NO. 114:** Any and all documents and things relating to generic competition or potential competition for LIPITOR® or to preventing generic entry of LIPITOR® on to the U.S. market.
>
> **REQUEST NO. 115:** Any and all documents and things relating to "Life Cycle Management" of LIPITOR®.
>
> **REQUEST NO. 122:** All documents and things regarding any authorized generic entry agreements, licenses and/or contracts Plaintiffs have entered into with any other drugs which are subject to a patent challenge.
>
> **REQUEST NO. 123:** All documents and things regarding any agreements, licenses and/or contracts relating to any agreement reached between Plaintiffs and any third-party regarding the marketing of generic versions of Plaintiffs' atorvastatin products, including but not limited to any authorized generic entry agreement.

(*Id*. at Req. Nos. 114-115 and 122-123). On January 14, 2010, Pfizer propounded its responses to Apotex's Rule 34 requests, in which it lodged numerous objections to Apotex Request Nos. 114-115 and 122-123 and refused to produce any responsive documents. (Alul Dec. Ex. D, Pls.' Objections and Resps. to Defs.' First Set of Reqs. for the Produc. of Docs. and Things, Pfizer's Resps. to Apotex Req. Nos. 114-115 and 122-123). Pfizer's main objection to producing

[2] All references to "Alul Decl." shall be to the Declaration of Andrew M. Alul, Esq. submitted concurrently herewith.

documents responsive to Apotex Request Nos. 114-115 and 122-123 was that the documents sought were irrelevant to the claims and defenses raised in the action. (*Id*.)

On March 2, 2010, Apotex sent Pfizer a letter detailing Pfizer's deficient responses to Apotex's first sets of discovery requests, including Pfizer's deficient responses to Apotex Request Nos. 114-115 and 122-123. (Alul Decl. Ex. E, Mar. 2, 2010 letter from A. Alul to R. Hutz 15-16). Apotex explained that the documents sought in Apotex Request Nos. 114-115 and 122-123—the third-party generic atorvastatin agreements and generic entry documents—were relevant to, *inter alia*, issues such as secondary considerations of non-obviousness, such as commercial success, licensing and acquiescence, that Pfizer was expected to raise in response to Apotex's obviousness invalidity defense and counterclaim, and also relevant to the issue of irreparable harm in connection with Pfizer's prayer for a permanent injunction. (*Id*.)

Pfizer responded on March 16, 2010, essentially maintaining its objections and refusal to produce documents responsive to Apotex Request Nos. 114-115 and 122-123. (Alul Decl. Ex. F, Mar. 16, 2010 letter from R. Hutz to A. Alul 25). On June 4, 2010, Apotex followed up with an additional letter to Pfizer on its deficient discovery request responses that again stressed the relevancy of the documents sought by Apotex Request Nos. 114-115 and 122-123, and that proposed a meet and confer. (Alul Decl. Ex. G, June 4, 2010 letter from A. Alul to R. Hutz).

Thereafter, in accordance with Local Civil Rule 37.2, a telephonic meet and confer was held between the parties on June 17, 2010, in an attempt to resolve outstanding deficiencies in Pfizer's responses to Apotex discovery requests and similar concerns Pfizer had with Apotex's responses to Pfizer's first sets of discovery requests. Compromises were reached on discovery benefitting both parties. However, without any support in law or fact, Pfizer maintained its refusal to produce third-party generic atorvastatin agreements and generic entry documents

responsive to Apotex Request Nos. 114-115 and 122-123.

ARGUMENT

I. Legal Standard.

Rule 26(b)(1) of the Federal Rules of Civil Procedure allows the parties to "obtain discovery regarding any non-privileged matter that is relevant to any party's claim or defense—including the existence, description, nature, custody, condition, and location of any documents or other tangible things and the identity and location of persons who know of any discoverable matter." Relevancy under Rule 26(b)(1) is liberally construed, *see* 8 CHARLES ALLAN WRIGHT & ARTHUR R. MILLER, FEDERAL PRACTICE AND PROCEDURE § 2008 at 99 (2d ed. 2004), to encompass "any matter that bears on, or that reasonably could lead to other matter that could bear on, any issue that is or may be in the case," *Oppenheimer Fund, Inc. v. Sanders*, 437 U.S. 340, 351 (1978); *see also Scott v. Edinburg*, 101 F. Supp. 2d 1017, 1021 (N.D. Ill. 2000) ("discovery . . . is 'widely recognized as one that is necessarily broad in its scope in order to allow the parties essentially equal access to the operative facts.'") (citations omitted).

II. The Third-Party Generic Atorvastatin Agreements Apotex Seeks Are Non-Privileged And Relevant And Should Therefore Be Produced.

A. The documents are not privileged.

As an initial matter, the third-party generic atorvastatin agreements Apotex is seeking in response to Apotex Request Nos. 122-123 are not confidential or privileged communications between Pfizer and its attorneys, nor are they documents that reflect such confidential or privileged communications. And nor could they be. Rather, these documents concern negotiations and/or agreements entered into between Pfizer and ***third-parties*** regarding generic atorvastatin. There can be no legitimate claim of attorney-client privilege for these documents, or any other privilege or immunity for that matter.

B. The documents are clearly relevant.

As set forth above, Pfizer has sued Apotex for infringement of the '667 patent; in turn, Apotex has asserted invalidity and noninfringement defenses and filed a counterclaim with invalidity and noninfringement counts directed to the '667 patent. As also set forth above, Apotex has twice laid out in painstaking detail its invalidity defenses to the '667 patent, which include a defense under 35 U.S.C. § 103(a) for obviousness of the '667 patent in view of the prior art. In turn, in its response to Apotex Interrogatory No. 6, Pfizer has stated that it intends to rely upon secondary considerations of non-obviousness in order to rebut the obviousness portion of Apotex's invalidity defense and counterclaim count. (Alul Decl. Ex. H). Purported secondary considerations of non-obviousness include commercial success, long-felt need, licensing by competitors, acquiescence, copying and failure of others. *KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. 398, 406 (2007); *In re Rouffet*, 149 F.3d 1350, 1355 (Fed. Cir. 1998); *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1538-39 (Fed. Cir. 1983).

Any settlement agreements Pfizer has entered into with third-parties regarding generic atorvastatin are clearly and unquestionably relevant to this case and, in particular, any secondary considerations that Pfizer may attempt to rely on. Pfizer's settlement agreement with Ranbaxy, for instance, which delays Ranbaxy's entry onto the atorvastatin market ***for over twenty (20) months after the date Ranbaxy would have otherwise been able to enter the market*** (March 24, 2010, the expiration date of U.S. Patent No. 4,681,893 plus pediatric exclusivity), is relevant to Apotex's invalidity defense and counterclaim count to the '667 patent for numerous reasons. First, the settlement agreement may have included a license Ranbaxy took from Pfizer on the '667 patent to allow Ranbaxy to make and use (but not commercially market) atorvastatin in the United States. Pfizer could possibly rely on the settlement agreement and license in this lawsuit

in an attempt to rebut Apotex's obviousness charge and, therefore, Apotex is entitled to discovery on the settlement agreement to see if such a license is included and, if so, to show that Ranbaxy decided to settle and take a license for reasons other than paying tribute to the '667 patent. *See Rouffet*, 149 F.3d at 1355; *Stratoflex*, 713 F.2d at 1538-39; *see also Am. Standard, Inc. v. Pfizer, Inc.*, MISC. 87-1-73-IP, 1988 WL 156152, at *3 (S.D. Ind. July 8, 1988) (Settlement agreement patent owner reached with third-party involving the patent-in-suit was relevant because it included a license which could be used by the patent owner to rebut the defendant's obviousness charge). Furthermore, the Federal Circuit has held that licenses entered into as a consequence of litigation are due less deference, *Pentec, Inc. v. Graphic Controls Corp.*, 776 F.2d 309, 316 (Fed. Cir. 1985), and therefore the Pfizer-Ranbaxy settlement agreement, which would shed light on why Ranbaxy took a license from Pfizer, is clearly relevant. Indeed, settlement agreements in patent cases are always relevant to whether the patent owner can rely on secondary considerations like acquiescence, licensing, and commercial success and, if so, to what extent. Simply put, Pfizer cannot sue Apotex on the '667 patent and rely on secondary considerations of non-obviousness to rebut Apotex's obviousness charge, while at the same time refusing to produce agreements reached on that same patent with others that reveal who is respecting that patent and the reasons why.

The second reason the settlement agreements Pfizer has with third-parties involving generic atorvastatin are relevant to this case has to do with requirements imposed by law on Pfizer should it choose to rely upon commercial success in order to rebut Apotex's obviousness defense. Specifically, for evidence of commercial success to be given substantial weight, there must be a nexus between the evidence and the merits of the claimed invention. *See Stratoflex*, 713 F.2d at 1539. With respect to the settlement agreement Pfizer entered into with Ranbaxy,

Pfizer may argue that any commercial success Lipitor® may enjoy is tied to the '667 patent as evidenced by Ranbaxy's willingness to stay off the market during the life of the '667 patent. Again, Apotex is entitled to discovery on the settlement agreement to show that Ranbaxy decided to settle and take a license for reasons other than paying tribute to the '667 patent. *See Stratoflex*, 713 F.2d at 1538-39; *see also Am. Standard*, 1988 WL 156152, at *3.

Next, under Rule 26(b)(1), "[f]or good cause, the court may order discovery of any matter relevant to the subject matter involved in the action." Pfizer has sued Apotex for infringement of the '667 patent, and Apotex is entitled to discovery that may assist Apotex in its defenses. Settlement agreements Pfizer has entered into with third-parties involving generic atorvastatin may show that Pfizer has misused the '667 patent in an anti-competitive way. Specifically, with respect to the settlement agreement Pfizer reached with Ranbaxy, as pointed out in Plaintiffs' motion to dismiss brief (D.I. 56), Ranbaxy was the first ANDA-filer for Lipitor® and the first to submit Paragraph IV certifications for all five listed Orange Book patents. (D.I. 56, Pls.' MTD Br. 7). As such, and as Pfizer concedes, Ranbaxy has secured eligibility under for the 180-day generic exclusivity period specified in 21 U.S.C. § 355(j)(5)(B)(iv) (2000)[3]. (*Id.*) Thus, by virtue of its Paragraph IV certifications, Ranbaxy secured 180-day exclusivity that will indefinitely delay the approval of subsequent applicants, like Apotex, for at least 180 days after Ranbaxy begins commercial marketing (if it ever does so), or favorable court decisions on all such patents by other applicants. 21 U.S.C. § 355(j)(5)(B)(iv)(I)-(II) (2000). At least one court has recognized in the ANDA-context that a settlement agreement that delays a first-filer's market entry, thus maintaining a "bottleneck" on

[3] For reasons set forth in Apotex's opposition brief (D.I. 68) to Pfizer's motion to dismiss, the provisions of the Hatch-Waxman Act pertaining to the 180-day generic exclusivity period prior to amendment by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 apply to this case. (D.I. 68, Apotex's MTD Opp'n Br. 3 n.1).

regulatory approval of subsequent ANDAs, is evidence of patent misuse and therefore discoverable. *Key Pharms., Inc. v. ESI-Lederle, Inc.*, No. CIV. A. 96-1219, 1997 WL 560131, at *2-4 (E.D. Pa. Aug. 29, 1997). In the *Key Pharmaceuticals* case, the court found persuasive the ANDA-filer's argument that the brand drug company "may have intentionally delayed the start of [the first ANDA-filer's] 180 day period, by placing restrictions on when [the first ANDA-filer] may commercially market its product and thereby further delay defendant's entry into the market." *Id*. at *4 (citation omitted). The court went on to state that "[i]f this be the case, this agreement may be an illegal restraint on trade and constitute patent misuse." *Id*. (*citing, generally, Morton Salt Co. v. G.S. Suppiger Co.*, 314 U.S. 488 (1942); *Compton v. Metal Prods., Inc.*, 453 F.2d 38 (4th Cir. 1971)); *see also Senza-Gel Corp. v. Seiffhart*, 803 F.2d 661, 668 (Fed. Cir. 1986) (an antitrust violation by a patentee constitutes patent misuse). Patent misuse is an equitable defense that renders a patent unenforceable. *See C.R. Bard, Inc. v. M3 Sys., Inc.*, 157 F.3d 1340, 1372 (Fed. Cir. 1998). It is also a complete defense to any claim by Pfizer for equitable relief, including the permanent injunctive relief that Pfizer seeks here.

Here, as stated earlier, Pfizer has managed, through a settlement agreement, to keep Ranbaxy off the market over twenty months after the date it would have been allowed to go to market after defeating U.S. Patent No. 5,273,995 ("the '995 patent;" the patent from which the '667 patent reissued). That is, after defeating the '995 patent, assuming all other FDA requirements were met, Ranbaxy would have been allowed to go to market with its generic atorvastatin product on March 24, 2010; somehow, and without explanation, Pfizer was able to convince Ranbaxy to stay off the market until November 30, 2011.[4] Apotex is entitled to

[4] *See* D.I. 71, April 13, 2009 Declaration of Andrew M. Alul, Esq. Ex. I, Pfizer Inc., Quarterly Report (Form 10-Q), at 45 (June 29, 2008); *id*. at Ex. J, Ransdell Pierson, *Pfizer, Ranbaxy Deal Would Delay Generic Lipitor*, REUTERS, June 18, 2008, http://www.reuters.com/article/innovationNews/idUSN1841865420080618).

discovery of the settlement agreement to determine if the terms of the agreement intentionally delayed the entry of Ranbaxy's atorvastatin product. *Key Pharms.*, 1997 WL 560131, at *3-4.

Last, any settlement agreements Pfizer has reached with third-parties may be relevant to Pfizer's motion to dismiss (D.I. 113), decided by the Court on June 30, 2010.[5] Specifically, Pfizer argued in its motion to dismiss brief that "Pfizer has given no indication that it will ever sue Apotex or any other party on the ['104, '156, and '971 patents]." (D.I. 56, Pls.' MTD br. 13). But did those patents, which Pfizer never sued Ranbaxy on, have anything to do with why Ranbaxy was willing to stay off the market for over twenty (20) months after it otherwise would have been allowed to go to market? If so, this would severely undercut the prime justification advanced by Pfizer in support of its motion to dismiss Apotex's counterclaims.

C. Settlement agreements are generally discoverable, and there is no "settlement privilege" under Federal law.

At the meet and confer held by the parties, counsel for Pfizer argued that any settlement agreements Pfizer has entered into with third-parties should be shielded from discovery under a "settlement privilege." But there is no "settlement privilege" recognized under Federal law; in fact, courts have uniformly rejected the assertion of such a non-existent privilege. *See Newman & Assocs. v. J.K. Harris & Co.*, No. 04Civ.9264(RJH)(MHD), 2005 WL 3610140, at *2 (S.D.N.Y. Dec. 15, 2005) (collecting cases rejecting the assertion of a "settlement privilege"). More importantly, this Circuit has rejected such a privilege. *See In re Gen. Motors Corp. Engine Interchange Litig.*, 594 F.2d 1106, 1124 n. 20 (7th Cir. 1979). Indeed, courts have routinely

[5] Although this Court denied Pfizer's motion to dismiss, **Pfizer has expressly represented that it intends to seek reconsideration of the Court's Order**. (See Alul Decl. Ex. J. July 7, 2010 letter from R. Hutz to A. Alul).

ordered the production of relevant settlement agreements.[6]

Moreover, the fact that settlement agreements Pfizer has reached with third-parties regarding generic atorvastatin may be confidential does not shield those agreements from discovery. *Leland*, 253 F.R.D. at 523 ("[T]he simple fact that the parties to the settlement agreement agreed to its confidentiality does not shield it from discovery." (internal quotations marks omitted) (quoting *Conopco, Inc. v. Wein*, No. 05Civ.9899(RCC)(THK), 2007 WL 1040676, at *5 (S.D.N.Y. April 4, 2007)). Courts have held this is especially true where there is a confidentiality order in place. *See, e.g. Leland*, 253 F.R.D. at 523. While the parties in this case are still in the process of negotiating a discovery confidentiality order, they have tentatively agreed to proceed with discovery by producing documents on an outside counsels' eyes only basis pending entry of a discovery confidentiality order. (Alul Decl. Ex. I, June 11, 2010 letter from D. Mulveny to A. Alul). This is not about Apotex gaining a competitive advantage over Pfizer—per the terms of the confidentiality agreement in place between the parties, Apotex will not see any settlement agreements produced by Pfizer. This is solely about Apotex's litigation counsel being able to adequately defend its client against Pfizer's infringement claim on the '667 patent. *See Truswal Sys. Corp. v. Hydro-Air Eng'g Inc.*, 813 F.2d 1207, 1211 (Fed. Cir. 1987) (order limiting disclosure to counsel adequately protected against disclosure of the confidential information to competitors).

[6] *Bd. of Trs. of Leland Stanford Junior Univ.*, 253 F.R.D. 521, 522-23 (C.D. Cal. 2008) (rejecting assertion of federal privilege preventing discovery agreements and ordering plaintiff to produce settlement agreement entered into with another defendant); *Abbott Diabetes Care Inc. v. Roche Diagnostics Corp.*, No. C05-03117 MJJ, 2007 WL 4166030, at *3-4 (N.D. Cal. Nov. 19, 2007) (same); *Rates Tech. Inc. v. Cablevision Sys. Corp.*, No. 05-CV-3583 (DRH)(WDW), 2006 WL 3050879, at *3-4 (E.D.N.Y. Oct. 20, 2006) (same and rejecting any heightened standard to the discoverability of settlement agreements); *Newman*, 2005 WL 3610140, at *2-4 (rejecting privilege assertion and ordering production of settlement agreement); *Am. Standard*, 1988 WL 156152, at *2-4 (ordering production of settlement agreement); *Key Pharms.*, 1997 WL 560131, at *2-4 (settlement agreement ordered produced in ANDA case).

D. Pfizer itself has sought discovery of settlement agreements in the past.

For Pfizer to argue irrelevance or some sort of privilege exempting from discovery any third-party generic atorvastatin agreements is entirely hypocritical in light of the fact that Pfizer has in the past successfully compelled the production of a settlement agreement during a patent suit against a competitor in orthopedic bone implants. *See Am. Standard*, 1988 WL 156152, at *1-4. In the *American Standard* case, Pfizer advanced at least two of the relevancy arguments being advanced by Apotex here—that the third-party generic atorvastatin agreements being sought here, including the Pfizer-Ranbaxy settlement agreement—are relevant to secondary considerations of nonobviousness such as commercial success and licensing. *Id*. at *2. As in the *American Standard* case, confidentiality will be safeguarded by limiting disclosure only to Apotex's outside counsel (per agreement in place between the parties, Alul Decl. Ex. I). *Am. Standard*, 1988 WL 156152, at *4. Pfizer has no legitimate reason to withhold the third-party generic atorvastatin agreements Apotex is seeking, and should therefore be compelled to produce them.

III. The Generic Entry Documents Apotex Seeks Are Non-Privileged And Relevant And Should Therefore Be Produced.

A. The documents are not privileged.

The generic entry documents Apotex is seeking in response to Apotex Request Nos. 114-115 are not confidential communications between Pfizer and its attorneys, or documents that reflect such confidential communications. Apotex does not believe there is any disagreement between the parties on this point.

B. The documents are clearly relevant.

The generic entry documents Apotex seeks include market share projections, strategy plans, life-cycle plans, and documents reflecting any anticipated reaction by Pfizer to generic

entry. These documents are clearly relevant to whether or not Pfizer would be irreparably harmed if Apotex were to enter the atorvastatin market prior to expiration of the '667 patent—from the meet and confer held between the parties on June 17, it is Apotex's belief that the parties do not dispute this point. They are also clearly relevant to the issue of commercial success, and whether there is any nexus between the claimed invention and the financial success of atorvastatin. As best as Apotex can tell, the dispute between the parties about the relevancy of the generic entry documents centers on whether Pfizer must prove irreparable harm in connection with its prayer for permanent injunctive relief. Specifically, it appears that Pfizer position is that, if Apotex's ANDA is found to infringe the '667 patent, then the Drug Price Competition and Patent Term Restoration Act of 1984 ("Hatch-Waxman Act") mandates that Apotex be permanently enjoined from infringing the '667 patent—without needing to prove irreparable harm.

However, Pfizer's position has no support in either the Hatch-Waxman Act or case law interpreting same. The relevant provision of the Hatch-Waxman Act dealing with remedies for patent infringement by the submission of an ANDA are codified at 35 U.S.C. § 271(e)(4). The specific provision dealing with injunctive relief is § 271(e)(4)(B), which reads as follows:

> § 271(e)(4) For an act of infringement described in [§ 271(e)(2)] . . .
>
> (B) injunctive relief may be granted against an infringer to prevent the commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of an approved drug or veterinary biological product . . . .

The language used, "may be granted," is permissive rather than mandatory. The general injunctive relief provision in the patent statute, 35 U.S.C. § 283, uses this same permissive language. In *eBay v. MercExchange*, the Supreme Court held that:

> According to well-established principles of equity, a plaintiff seeking a permanent injunction must satisfy a four-factor test before a court may grant such

> relief. A plaintiff must demonstrate: (1) that it has suffered an irreparable injury; (2) that remedies available at law, such as monetary damages, are inadequate to compensate for that injury; (3) that, considering the balance of hardships between the plaintiff and defendant, a remedy in equity is warranted; and (4) that the public interest would not be disserved by a permanent injunction. . . . The decision to grant or deny permanent injunctive relief is an act of equitable discretion by the district court, reviewable on appeal for abuse of discretion. . . .
>
> ***These familiar principles apply with equal force to disputes arising under the Patent Act.***

eBay, 547 U.S. at 391 (internal citations omitted) (emphasis added). The Supreme Court went on to hold that the categorical granting of permanent injunctive relief upon a finding of infringement is error. *Id*. at 394. There is no authority holding that 35 U.S.C. § 271(e)(4)(B) is to be applied any differently than for permanent injunctions sought in other patent cases. In fact, in an ANDA case decided post-*eBay*, the District of New Jersey expressly applied the four-factor test in deciding whether to grant a permanent injunction. *Ortho-McNeil Pharm., Inc. v. Mylan Labs. Inc.*, Civil Action Nos. 04-1689, 06-757, 06-5166, 2007 WL 869545, at *1 (D.N.J. March 20, 2007).

Pfizer has no legitimate reason to withhold the generic entry documents sought by Apotex and the Court should therefore compel Pfizer to produce those documents.

CONCLUSION

For the foregoing reasons, Apotex's Request Nos. 114-115 and 122-123 seek relevant, non-privileged documents and Pfizer should be compelled to produce documents responsive to those requests, including third-party generic atorvastatin agreements and generic entry documents.

Dated: July 9, 2010.

Respectfully submitted,

APOTEX INC. AND APOTEX CORP.

By: */s/ Andrew M. Alul*
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CERTIFICATE OF SERVICE

I, Andrew M. Alul, an attorney, hereby certify that on this 9th day of July, 2010, a true and correct copy of the foregoing MEMORANDUM IN SUPPORT OF APOTEX INC. AND APOTEX CORP.'S MOTION TO COMPEL DISCOVERY was filed with the Clerk of the Court using the Electronic Case Filing (ECF) system which will send notification of such filing via electronic mail to all counsel of record.

/s/ Andrew M. Alul

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